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EXAMINER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102/103***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 1-3, 9, 12, 14-17, 19-20, 26-27, 31, 36-39, 122, 136-139, 143 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Easterbrook et al. (US 6,238,334).

4. . Easterbrook discloses a method and apparatus for a heart assist device comprising a cuff with a first layer and second layer as seen in Fig. 1. Easterbrook discloses an internal inflatable bladder between the first and second layers that would deform the first layer to assist ventricular contractions. Easterbrook also discloses an uninstalled and installed configuration such that when uninstalled the first and second ends of the second layer are separate and when installed the ends are coupled as seen in Fig. 1 and Fig. 8. Easterbrook discloses the compliant first layer may be constructed of a silicone rubber (Col. 6, line 63) which examiner considers having material properties consistent with 500% elongation.

5. Easterbrook further teaches a material with a higher percentage elongation property may be used; therefore in the alternative it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Easterbrook with a first layer material that has an elongation of 500% since such a modification would provide the predictable results of increasing compliance of the bladder to the heart and distributing more evenly a pressure across the heart. Moreover, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Easterbrook with a material having a minimum elongation percentage of 500% since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art, *In re Aller*, 105 USPQ 233, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended uses as a matter of obvious design choice, *In re Leshin*, 125 USPQ 416, and since it has been held that discovering the optimum value of a result effective variable involves only routine skill in the art, *In re Boesch* 617 F.2d 272, 205 USPQ 215.
6. With regard to claim 2, the first layer radially deforms as seen in fig. 8.
7. With regard to claim 3 and 137, Easterbrook discloses the first layer to be made of a polyurethane and the second layer to be made of a plastic polymer such that the first layer is deformed and the second layer does not (Col. 5, line 65- Col. 7, line 5).
8. With regard to claim 9 and 12, Easterbrook discloses a reinforcement element coupled to the second layer composed of nylon (Col. 14, line 23).

9. With regard to claim 14 and 15, Easterbrook discloses the first and second layers being connected about the perimeter of the first layer and second layer as seen in fig. 1, where the portion of the perimeter of the first layer is about the length of the first layer and the perimeter of the second layer is about the width.

10. With regard to claim 16 and 17, the outer cuff extends beyond the bladder for coupling attachment as seen in fig. 1.

11. With regard to claim 19, the length of the outer cuff is sufficient to completely encircle the heart and overlap to couple each end as seen in Fig. 1 and 8.

12. With regard to claim 36 -38, Easterbrook discloses the first layer having a rectangular spherical shape, and the second layer to be rectangular and planar. These shapes are similar in that they are both rectangular; however the curved surface of the first layer distinguishes the two as seen in Fig. 8.

13. With regard to claim 122, Easterbrook discloses a conduit, Fig. 1, 22, for supplying fluid to the bladder from some pumping mechanism for inflating the cuff.

14. With regard to claim 136, Easterbrook discloses a hook and loop method for coupling the cuff ends as seen in Fig. 1; 15 and 16. In such a configuration any coupling of the ends at their more respective distal ends and a second coupling at their more proximal ends will represent a plurality of coupling positions.

15. With regard to claims 26, 31 and 138, Examiner considers each hook and each loop of the first and second ends respectively to represent a tab. As illustrated in Fig. 1, the sum of the widths of the hooks of the first end and the loops of the second end, do

not equal the width of the cuff, as evidenced by the empty spaces of the backing of the cuff showing through.

16. With regard to claim 27 and 143, Easterbrook discloses the cuff being disposed about the heart, which includes blood vessel and the coupling of the hooks and loops (tabs) of the first and second ends.

17. With regard to claim 147-151, 154, Easterbrook discloses a plurality of inlet conduits coupled to the cavity (Fig. 4, 30) where each inlet conduit lumen appears to have the same diameter. Further Easterbrook discloses another inlet lumen that has an apparent different diameter (Fig. 1, 46).

18. With regard to claim 152-153, Easterbrook discloses the conduit having a first and second diameter as seen in Fig. 3, where the conduit's diameter is larger at the opening by the cavity and smaller at the distal end.

19. With regard to claim 156-158, Easterbrook discloses that the fluid may be water, carbon dioxide, or an inert gas (Col. 9, line 34).

### ***Claim Rejections - 35 USC § 103***

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. Claim 4, 7-8, 10-11, 13, 18, 28-30, 32-34, 140-142, 144-146, 159-160 and 169-170 are rejected under 35 U.S.C. 103(a) as being unpatentable over Easterbrook.

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22. With regard to claims 4, 7-8, 10-11, 155 and, Easterbrook discloses the claimed invention except for a first silicone elastomer and a second silicone elastomer with material properties of 5-50 A and 500% elongation of the first silicon elastomer and 65-95 A and 400% percent elongation of the second elastomer and a reinforcement of polyester, nylon, stainless steel, platinum or other alloys of the second elastomer layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Easterbrook with first silicone elastomer and a second silicone elastomer with material properties of 5-50 A and 500% elongation of the first silicon elastomer and 65-95 A and 400% percent elongation of the second elastomer with a reinforcement element of polyester, nylon, stainless steel, platinum or other alloys, since it has been held to be within general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin*, 125 USPQ 416.

23. With regards to Claim 13, Easterbrook discloses the claimed invention except for the first and second layers to be of silicone neoprene and copolymers comprising styrene and butadiene. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Franchi with the first and second layers to be of silicone neoprene and copolymers comprising styrene and butadiene, since it was known in the art that the first and second layers to be of silicone neoprene and copolymers comprising styrene and butadiene is used to provide a biocompatible elastically deformable material for use in a vascular assist device.

24. With regards to claim 18, Easterbrook discloses the claimed invention but fails to teach a width of the first layer to be less than the width of the second layer. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to modify the system as taught by Easterbrook with a width of the first layer to be less than the width of the second layer, since Applicant has not disclosed that the width of the first layer to be less than the width of the second layer provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore would have expected Applicant's invention to perform equally well with widths of the first layer and second layer to being substantially equal as taught by Easterbrook, because it provides the ability to encompass the vessel completely and since it appears to be an arbitrary design consideration which fails to patentability distinguish over Easterbrook.

25. Therefor it would have been an obvious matter of design choice to modify Easterbrook to obtain the invention as specified.

26. With regard to claims 28-30, 32-34, 140-142, and 144-146 Easterbrook fails to teach a tab spacing profile where the sum of the widths of the tabs equals the total width of the device or coupling a side branch such as the aorta of vena cava with the tab configuration. It would have been obvious to one having ordinary skill in the art at the time the invention was made since such a modification would provide the predictable results of ensuring a proper seal and engagement of the device about the heart and various branches to greater improve hemodynamic benefit and localized therapy.



27. With regard to claim 159-160, Easterbrook discloses the claimed invention except for the use of gas as the fluid along with the material properties of the gas or specific gases. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Easterbrook since it was known in the art that the use of a gas along with the material properties of the gas or specific gases and the material properties of gas are used to provide a safe alternative to an actual liquid. IT has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

28. With regard to claims 169 and 170, Easterbrook discloses the claimed invention but fails to teach a reinforcement element for the conduits. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to modify the system as taught by Easterbrook with a reinforcement of the conduit, since Applicant has not disclosed that reinforcing the conduits provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore would have expected Applicant's invention to perform equally well with reinforced conduits made of tygon, silicon, etc. as taught by Easterbrook, because it provides resistance to kinking and collapsing and since it appears to be an arbitrary design consideration which fails to patentability distinguish over Easterbrook.

29. Therefor it would have been an obvious matter of design choice to modify Easterbrook to obtain the invention as specified.

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30. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Easterbrook in view of Walsh et al (US 6,902,522).

31. Easterbrook discloses the claimed invention except for coating the device with a tissue growth polymer such as poly-lysine. Walsh teaches that it is known to use poly-lysine in coating a vascular assist device as set forth in Col. 19, line 1-21 to provide receptor cell recruitment and increase patient acceptance of the implant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Easterbrook with coating the device with a tissue growth polymer such as poly-lysine, since such a modification would provide the system with a device that is coated with tissue growth polymer such as poly-lysine for providing receptor cell recruitment and increase patient acceptance of the implant.

32. Claims 21, 128-129 and 161-164 are rejected under 35 U.S.C. 103(a) as being unpatentable over Easterbrook as applied above in view of Franchi.

33. With regard to claim 21-22, Easterbrook discloses the invention as claimed but fails to teach the cuff being placed around the aorta vena cava, or intercostals veins. Franchi teaches that it was known in the art that a vascular assist cuff device is capable of being placed around the aorta as set forth in the abstract for providing the predictable result of achieving the greatest hemodynamic benefit. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Easterbrook with engaging the internal vasculature of the aorta, vena cava or intercostals veins since applying the device to these vessels would

provide the predictable results of achieving the greatest hemodynamic benefit to a patient.

34. Easterbrook discloses the invention as claimed but fails to teach the pump being pump being pulsatile and the entire system of the pump, cuff and conduit being implantable. Franchi teaches an implantable cuff and pump system as set forth in (Col. 3, line 47-59 for providing the predictable results of synchronous pumping with the natural heart rhythm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Easterbrook with an implantable pulsatile pump for providing the predictable results of synchronous pumping with the natural heart rhythm.

35. With regard to claims 161-164, Easterbrook discloses the invention as claimed but fails to teach a fluid volume compensator that is in fluid flow path between the pump and the cavity, wherein the compensator adjust volume ported into the cavity and allow replenishment of the fluid system. Franchi teaches that it is known to use a fluid volume compensator that is in fluid flow path between the pump and the cavity, wherein the compensator adjust volume ported into the cavity and allow replenishment of the fluid system as set forth in (Col. 3, line 47- Col. 4, line 15; Fig. 1, Fig. 4) for providing the predictable results of reducing the effort of the heart to produce a diastole and systole. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Easterbrook with a fluid volume compensator that is in fluid flow path between the pump and the cavity, wherein the compensator adjust volume ported into the cavity and allow replenishment of the fluid

system since such a modification would provide the predictable results of reducing the effort of the heart when producing a diastole and systole.

36. Claims 123-127 and 130-134 are rejected under 35 U.S.C. 103(a) as being unpatentable over Easterbrook in view of Freed (US 5,169,379).

37. With regard to claims 123-127 and 130-134, Easterbrook discloses the claimed invention but fails to disclose what kind of signal is obtained in the system or if the signal is indicative of electrical, systole, diastole, aortic pressure, arterial pressure, or venous pressure from what kind of sensor. Freed teaches that it is known to observe electrical cardiac signals and aortic pressure, which is inherently indicative of systolic pressure, and arterial pressure, as set forth in Col. 6, line 46, for providing the predictable results of generating optimal pumping parameters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Easterbrook with a signal indicative of electrical, systole, diastole, aortic pressure, arterial pressure, or venous pressure, since it was known in the art that electrical, systole, diastole, aortic pressure, arterial pressure, or venous pressure, as taught by Freed, since such a modification would provide the system with signal is indicative of electrical, systole, diastole, aortic pressure, arterial pressure, or venous pressure from what kind of sensor for providing indication of cardiac performance and would provide the predictable results of generating optimal pumping parameters.

38. Claims 165-168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Easterbrook in view of Okuzumi (US 6,587,734).

39. With regard to claims 165-168, Easterbrook discloses the claimed invention except for coating the device with a material to enhance lubricity and reduce fluid loss. Okuzumi teach that it is known to coat a vascular assist device with a polyurethane to enhance lubricity and prevent loss of fluid as set forth in Col. 9, line 1-13, for providing increased lubricity so as not to rupture or shear vasculature. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Easterbrook with coating the device with a material to reduce fluid loss and provide lubricity, as taught by Okuzumi, since it was known in the art that coating the device with a material to reduce fluid loss and provide lubricity is used for allowing easier application of the device and prevent future invasive procedures to address lost fluid and/or ruptured or sheared vasculature.

#### ***Response to Arguments***

40. Applicant's arguments with respect to claims 1-34, 36-39, 136-170, have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

#### ***Conclusion***

41. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH STOKLOSA whose telephone number is (571)272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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